IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MYLAN PHARMACEUTICALS INC., Plaintiff, v. JANSSEN PHARMACEUTICALS, INC., Defendant.	C.A. No. 2:15-cv-2990-MAK

MYLAN PHARMACEUTICALS INC.'S OPPOSITION TO DEFENDANT JANSSEN PHARMACEUTICALS, INC.'S MOTION TO DISMISS THE COMPLAINT

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I. INTRODUCTION

The relief sought by Janssen Pharmaceuticals, Inc. ("Janssen") in its Motion to Dismiss is contrary to the letter and spirit of the Hatch-Waxman Act, and would harm the public by slowing the full competitive marketplace for generic versions of Janssen's drug, Concerta®.

Janssen asserts two bases for its motion to dismiss. They both should fail. First, it argues that Mylan Pharmaceuticals Inc.'s ("Mylan") Complaint seeking a declaratory judgment of the invalidity or non-infringement of U.S. Patent No. 8,629,179 ("the '179 patent") was a compulsory counterclaim to Janssen's Complaint against Mylan regarding a separate patent, U.S. Patent No. 8,163,798 ("the '798 patent). Janssen is wrong and cites no authority holding that a declaratory judgment counterclaim regarding one patent is ever compulsory in an infringement action based on a separately issued U.S. patent. Moreover, Mylan's declaratory judgment action is specifically authorized by the Hatch-Waxman Act.

Second, Janssen asserts that there is no subject matter jurisdiction over this action due to a covenant not to sue given to Mylan by Janssen pertaining to the '179 patent. Janssen's argument is directly contrary to settled controlling law. The Federal Circuit has addressed this issue and has specifically held that a substantial controversy remains with respect to a non-infringement or invalidity counterclaim in a Hatch-Waxman Act litigation despite the existence of a covenant not to sue. As explained in more detail below, a covenant not to sue is insufficient to trigger expiration of the first filer's market exclusivity under the Hatch-Waxman Act. The Federal Circuit has thus repeatedly and consistently held that a declaratory judgment action serves a valid and valuable public function in helping to prevent the "parking" of the market exclusivity provided to certain Abbreviated New Drug Application ("ANDA") filers notwithstanding a covenant not to sue. This is the situation addressed by Mylan's declaratory judgment action.

Accordingly, Janssen's motion should be denied.

II. FACTUAL BACKGROUND

Janssen's methylphenidate hydrochloride extended-release tablets are sold under the name Concerta® pursuant to New Drug Application ("NDA") No. 21-121. Upon FDA approval, the NDA holder causes patents that it deems can be asserted against a company seeking to market a generic version of its drug to be listed in the FDA's "Orange Book".[1] Janssen has caused six separately issued U.S. patents to be listed in the Orange Book for Concerta®, among them the '798 patent and the '179 patent owned by Alza Corporation ("Alza").

Mylan filed its ANDA No. 20-6726 seeking to bring its generic version of Concerta® to the U.S. market and timely delivered notice to Janssen and Alza of its Paragraph IV certifications for the '798 and '179 patents (among others) contending that those patents were either not infringed, were invalid or were unenforceable. *See* 21 U.S.C. §§ 355(j)(D)(i)(I)(cc), 355(j)(D)(i)(III).

Following receipt of this notice, Janssen and Alza filed suit on May 15, 2014, against Mylan in the U.S. District Court for the Northern District of West Virginia for infringement of the '798 patent only. Under the Hatch-Waxman Act, the filing of the ANDA with a Paragraph IV certification is deemed to be an artificial act of infringement sufficient to confer subject matter jurisdiction over the controversy despite the fact that the defendant has not actually made, sold or used the allegedly infringing product commercially in the United States. This provision, central to the fabric of the Hatch-Waxman Act, serves the public good by allowing for the resolution of patent disputes to take place on a track designed to be roughly parallel to that of the

[1] In its brief, Janssen curiously contends that "Mylan asserted that there are at least two patents covering the product that were at issue" (Def.'s Mem. in Support of its Mot. to Dismiss the Compl. [D.I. 13] ("Motion to Dismiss") at 1) when in fact it is Janssen who makes such an assertion. Mylan is required by the Hatch-Waxman Act to address each patent listed in the Orange Book. Thus, it is Janssen's actions that give rise to the present sequence of events.

FDA's consideration of the ANDA. Janssen's initiation of the West Virginia action effectuated a 30-month stay of FDA approval of Mylan's ANDA.

The parties executed a covenant not to sue pertaining to the '179 patent on or about November 10, 2014. While this gives Mylan certain assurances in accordance with its specific terms, a substantial controversy remains (as explained below) regarding the impact of the '179 patent on Mylan's ability to launch its ANDA product following the 30-month stay. This is ultimately to the detriment of not only Mylan, which may be unjustly excluded from the marketplace, but also the public, which will benefit from Mylan's competitive participation in the marketplace.

To prevent this result, Mylan has moved the District Court in West Virginia, seeking to add counterclaims of invalidity and non-infringement of the '179 patent. Janssen and Alza are opposing that motion (which is now fully briefed and pending before the court) as being untimely. Due to that opposition, Mylan filed the instant action to ensure that the significant issues related to the '179 patent and Mylan's ability to launch its ANDA product are heard by a court.

III. ARGUMENT

A. Mylan's Complaint Is Not Barred by the Compulsory Counterclaim Rules.

The present declaratory judgment action seeks to adjudicate the rights of the parties regarding the '179 patent. The West Virginia action was brought by Janssen and Alza solely pertaining to their claims regarding the '798 patent. There is no authority cited by Janssen in its brief holding that a declaratory judgment counterclaim as to one patent is compulsory in an infringement action based on another patent, and Mylan is aware of no such authority. Accordingly, Janssen's unsupported argument should be rejected.

It is axiomatic that each separately issued patent "establishes an independent and distinct property right," and is deemed by law to be a separate invention. *Kearns v. General Motors Corp.*, 94 F.3d 1553, 1555 (Fed. Cir. 1996) (holding that adjudication as to certain patents did not bar claims brought based on separately issued U.S. patents).[2] This same principal applied here dictates denial of Janssen's motion, and there is no authority suggesting otherwise.

Given the separate rights involved, it is unsurprising that case law is replete with examples where counterclaims for declaratory judgment on a separate patent were held not to be compulsory to a patent infringement case brought on a separate patent. The Third Circuit has rejected just such an argument. *See Measurements Corp. v. Ferris Instrument Corp.*, 159 F.2d 590, 594 (3rd Cir. 1947) (rejecting the contention that a counterclaim involving one patent was "by no means the same transaction or occurrence" involved in the claim on a different patent). Other examples throughout the country consistently show that Janssen's position "is not sound." *See McNeil Mach. & Eng'g Co. v. Nat'l Rubber Mach. Co.*, 222 F. Supp. 85, 86 (N.D. Ohio 1963) (rejecting claim that counterclaim was compulsory when based on a separate patent even though the patents involved relate to the same general subject of the invention); *Rubsam v. Harley C. Loney Co.*, 86 F. Supp. 350, 351 (E.D. Mich. 1949) (holding that, where the patents involved in the counterclaim were separate from the patents mentioned in the plaintiff's cause of action, the counterclaim was permissive and not compulsory); *Int'l Controls and Measurements Corp. v. Honeywell Int'l, Inc.*, No. 5:12-CV-1766 (LEK/ATB), 2013 WL 4805801, at *7 (N.D.N.Y. Sept. 9, 2013) (rejecting claim that counterclaims on different patents were

[2] The *Kearns* decision has also been applied to reject a "should have been brought" theory such as Janssen advances here because each patent gives rise to an independent and distinct cause of action. *See Scimed Life Sys v. Advanced Cardiovascular Sys., Inc.*, No. C 99-0112 MJJ, 1999 WL 33244568, at *1 (D. Minn. May 17, 1999); *Trading Technologies Int'l, Inc. v. BCG Partners, Inc.*, Nos. 10 C 715, 10 C 716, 10 C 718, 10 C 720, 10 C 721, 10 C 726, 10 C 882, 10 C 883, 10 C 884, 10 C 885, 10 C 929, 10 C 931, 2011 WL 3157304 (N.D. Ill. July 26, 2011).

compulsory because they involved the same products as were at issue in the original complaint); *see also Metallgesellschaft AG v. Foster Wheeler Energy Corp.*, 143 F.R.D. 553, 558 (D. Del. 1992) (determining that counterclaim on different patents was permissive and not compulsory).

Against this background, it is unsurprising that none of Janssen's authority stands for the proposition that a declaratory judgment counterclaim on one patent is a compulsory counterclaim to a complaint brought on a separate patent. Janssen's authority recites general, but unhelpful, rules that are not specific to the particular circumstances of this case. Most of Janssen's authority does not involve patents at all.[3] The cases Janssen cites that do involve patent litigation do not support Janssen's position. Two of these cases held that antitrust counterclaims based on the alleged improper procurement of the *same* patents asserted in infringement claims were compulsory. *Kimberly-Clark Worldwide, Inc. v. First Quality Baby Products, LLC*, No. 1:CV-09-1685, 2011 WL 743468, at *2 (M.D. Pa. Feb. 24, 2011); *Rohm and Haas Co. v. Brotech Corp.*, 770 F. Supp. 928, 929 (D. Del. 1991). In the third, the court held that a trade secret counterclaim was compulsory to a patent infringement complaint, but the defendant in that case did not contest the issue. *See Mopex, Inc. v. Am. Stock Exch., LLC*, No. 02 Civ. 1656(SAS), 2002 WL 342522, at *8 (S.D.N.Y. Mar. 5, 2002). And, finally, in *Polymer Indus. Prods. Co. v. Bridgestone/Firestone, Inc.*, the court simply held that an infringement counterclaim was compulsory to a declaratory judgment action for non-infringement of the *same* patent. 347 F.3d

[3] *See Baker v. Gold Seal Liquors, Inc.*, 94 S. Ct. 2504 (1974) (bankruptcy case for recovery of freight charges); *Southern Constr. Co. v. Pickard*, 83 S. Ct. 108 (1962) (Miller Act action against contractor and surety); *Vukich v. Nationwide Mut. Ins. Co.*, 68 Fed. Appx. 317 (3rd Cir. 2003) (breach of contract and misrepresentation actions); *Transamerica Occidental Life Ins. Co. v. Aviation Office of America, Inc.*, 292 F.3d 384 (3rd Cir. 2002 (reinsurance contract dispute); *Nasalok Coating Corp. v. Nylok Corp.*, 522 F.3d 1320, 1328 (Fed. Cir. 2008) (trademark infringement action holding that an invalidity counterclaim to an infringement action was not compulsory); *JSM at Tingley, LLC v. Ford Motor Co.*, No. 11-448, 2011 WL 6934852 (D.N.J. Dec. 30, 2011) (environmental cost recovery action).

935, 939 (Fed. Cir. 2003). Accordingly, none of Janssen's authority supports a departure from the settled rule that each patent is separate and distinct, nor does it support the proposition that Mylan's declaratory judgment claims for the '179 patent were compulsory in litigation involving the '798 patent.

In the Hatch-Waxman context, it makes even less sense to impose a compulsory counterclaim rule in these circumstances. Janssen and Alza elected to assert infringement of only one patent in the West Virginia litigation, yet obtained the full benefit of a 30-month stay on approval of Mylan's ANDA product as a result. Importantly, such an action does not prevent Janssen or Alza from later separately bringing an action against Mylan on any of the other Orange Book-listed patents should they later determine they want to pursue their rights under these patents. Accordingly, in similar fashion, the instant declaratory judgment action should not be precluded, as Mylan has now determined that the rights under the '179 patent should be adjudicated, and has properly followed the statutory prerequisites to initiate this action.

Moreover, Concerta® is a pre-Medicare Modernization Act ("MMA") drug. Under pre-MMA rules, the 180-day exclusivity period is patent-based, not product-based, such that the first ANDA applicant(s) is eligible for 180-day exclusivity separately with respect to each Orange Book-listed patent. *See* 21 U.S.C. § 505(j)(4)(B)(iv) (1984). The FDA cannot approve a second filer's (such as Mylan) application until after the expiration of all such exclusivity periods for each Orange Book-listed patent. As such, the rights being adjudicated in West Virginia on the '798 patent are even more separate and distinct from those of the '179 patent being litigated here. Indeed, as discussed in the next section below, the basis for subject matter jurisdiction with regard to the '179 patent is deemed to be separate and independent of the basis for such jurisdiction over other Orange Book-listed patents for Concerta®.

Janssen's final argument in its effort to invoke the compulsory counterclaim rule is based on a misapplication of Mylan's statements in support of being permitted to amend the counterclaims in the West Virginia action. (*See* Mot. to Dismiss at 8). The fact that it would be more convenient to litigate the '179 patent in West Virginia, and that Mylan has indicated a preference for doing so, does not make Mylan's present action on the '179 patent a compulsory counterclaim. Mylan's West Virginia motion to amend does not implicate the same standard as the compulsory counterclaim rules. Janssen's resistance to the judicial efficiency of such a consolidated action in West Virginia is directly contrary to its misguided complaint about judicial economy here. Rather, such resistance is indicative of Janssen's use of such considerations as a convenient weapon in its attempt to disrupt the legitimate efforts of Mylan to clear the pathway for the generic market for Concerta® in the U.S.

B. Janssen's Listing of the '179 Patent in the Orange Book Establishes the Existence of a Case or Controversy, Notwithstanding the Existence of the Covenant Not to Sue.

1. *The Pre-MMA Hatch-Waxman Provisions Will Prevent Mylan from Launching its Product Unless the First Filer on Each Orange Book-Listed Patent Has Launched its Own Product.*

Mylan seeks to launch its product prior to the expiration of the patents listed in the Orange Book for Concerta®. To do so, Mylan must obtain FDA approval, which can only be made effective 180 days after either (1) the first commercial marketing by the first filer for each patent listed in the Orange Book for Concerta®, or (2) the date of a court decision holding each such patent is invalid or not infringed. *See* 21 U.S.C. § 505(j)(4)(B)(iv) (1984).

The provisions of the Hatch-Waxman Act predating the implementation of the current post-MMA Hatch-Waxman statute apply to Concerta®, which means that the 180 day events

must be considered on a patent-by-patent basis.[4] There is a separate first filer for each patent listed in the Orange Book. The FDA cannot approve a second filer's (such as Mylan) application until expiration of the exclusivity periods for each Orange Book-listed patent. Because Mylan was not the first filer with respect to the '179 patent, it is blocked from marketing its product until the exclusivity period associated with that patent is triggered and expired. If there is no commercial launch by the first filer, the only way for Mylan to be able to trigger the start of the 180 day exclusivity period is through a court judgment.

2. *Federal Circuit Law Establishes that There Is Subject Matter Jurisdiction Over Mylan's Declaratory Judgment Claims.*

The Federal Circuit's *Caraco* line of cases makes clear that it is necessary for a generic manufacturer to obtain judgment on *all* Orange Book-listed patents. Otherwise, it will suffer injury from being unable to obtain FDA approval and subsequently launch its product. Janssen argues that there is no such jurisdiction because (1) there is no reasonable apprehension of suit due to the covenant not to sue, (2) Mylan's injury is speculative because it will not be injured, and (3) there is no injury traceable to Defendant. (*See* Motion to Dismiss at 10-11). All of these arguments must fail.

a. The Covenant Not to Sue Does Not Eliminate the Existence of a Case or Controversy.

The covenant not to sue does not negate the existence of a case or controversy under the Federal Circuit's precedent because it does not remove the threat of harm to be suffered by Mylan. The Federal Circuit has held that such a covenant will not moot a case or controversy if an ANDA applicant was not sued for infringement on each Paragraph IV-certified Orange Book patent. *See Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1296-97 (Fed. Cir.

[4] Under the post-MMA version of the Hatch-Waxman Act, the 180 day exclusivity period applies on a per-product basis, rather than on a per-patent basis.

2008) (holding declaratory judgment claims not moot despite a covenant not to sue on those same patents, and stating, "even after a covenant not to sue has been granted, the dispute as to infringement or invalidity of the relevant Orange-Book-listed patents constitutes 'a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.'" (quoting *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 126 (2007));[5] *Dey Pharma, LP v. Sunovian Pharms. Inc.*, 677 F.3d 1158, 1163-64 (Fed. Cir. 2012) (stating that an argument that a covenant not to sue moots a case would be "foreclosed by [the Federal Circuit's] contrary holding in *Caraco*").

The same rule holds true even when the parties have negotiated a covenant over the declaratory judgment patents. In the *Teva* case, the parties had negotiated a covenant not to sue on patents subject to the declaratory judgment claim. *Teva Pharms. USA, Inc. v. EISAI Co., Ltd.*, 620 F.3d 1341, 1345 (Fed. Cir. 2010). The Federal Circuit held that there was an actual controversy because the defendant there did not stipulate to the validity, infringement or enforceability of the patents at issue. *Id.* at 1347-48 & n.3 (citing *Caraco*, 527 F.3d at 1296-97).[6] The same facts are present here. Mylan agreed to the covenant not to sue covering the '179

[5] The Federal Circuit noted that a covenant not to sue issued in the ANDA context is unique compared to a covenant granted in the "ordinary" patent infringement context: "Clearly, in the ordinary infringement context, even when a patentee maintains that its patents are valid and infringed by a potential defendant, a covenant not to sue allows the recipient to enter the marketplace. Indeed, a covenant not to sue on a patent ensures that the covenant's recipient will not be liable for damages or subject to an injunction for infringement of that patent. ***However, in the Hatch–Waxman context, regardless of a covenant not to sue, a generic drug manufacturer cannot enter the market without FDA approval***." *Id.* at 1296 (emphasis added).

[6] This decision later was vacated and remanded as moot by the Supreme Court because the first filer had launched its product. *See Eisai Co., Ltd. v. Teva Pharms. USA, Inc.*, 131 S. Ct. 2991, 2991 (2011); *see also* Suggestion of Mootness, *Teva Pharms. USA, Inc. v. Eisai Co., Ltd.*, No. 08-2344 (HAA), ECF No. 70-1 (D.N.J. Dec. 20, 2010) (noting that Teva's claim was moot because the first filer, Ranbaxy, had launched its product). Although the declaratory judgment claim ultimately became moot, that was not until the date that the harm was removed by the first filer's commercial launch (and thus the start of its 180-day exclusivity period).

patent, but *never* stipulated to the validity, infringement or enforceability of the '179 patent therein or elsewhere. (*See generally* Ex. 1 to Mot. to Dismiss (covenant not to sue)). Under this clear Federal Circuit precedent, Mylan's agreement to the covenant not to sue decidedly does *not* eliminate the existence of a case or controversy.

b. Janssen's Listing and Maintenance of the '179 Patent in the Orange Book Support Jurisdiction over Mylan's Declaratory Judgment Claims.

Janssen's other arguments cannot defeat the subject matter jurisdiction over Mylan's claims. For there to be jurisdiction over a declaratory judgment claim, "the dispute [must] be definite and concrete, touching the legal relations of [the] parties . . . and . . . be real and substantial . . . ." *MedImmune*, 549 U.S. at 127; *see also generally Caraco*, 527 F.3d 1278. There are three simple requirements that must be fulfilled for subject matter jurisdiction to exist over a declaratory judgment patent claim bought under the Hatch-Waxman Act[7]: (1) the existence of a judicially cognizable injury-in-fact; (2) such injury is traceable to the NDA holder/patentee (*i.e.*, Janssen); and (3) the injury is redressable by a favorable judgment. *See Caraco*, 527 F.3d at 1291-94; *Teva*, 620 F.3d at 1346-48 (following *Caraco* under pre-MMA

[7] Although there is Federal Circuit case law addressing such jurisdiction over declaratory judgment counterclaims outside of the Hatch-Waxman context, that case law is inapplicable here due to the unique nature of the Hatch-Waxman framework. As opposed to the more "traditional" scenario in which patent infringement is based on affirmative acts committed, such as making or selling a patented product, under the Hatch-Waxman Act, there has only been a technical act of infringement due to the filing of an ANDA. 35 U.S.C. § 271(e)(2). Furthermore, an ANDA applicant is legally barred from marketing its product until receiving FDA approval to do so. 21 U.S.C. § 355(a). Such FDA approval will be withheld for subsequent ANDA filers until after the first filer(s) has either enjoyed 180 days of market exclusivity following a commercial launch or there has been a judgment that the patent for which that entity is a first filer is invalid or not infringed. *See* 21 U.S.C. § 505(j)(4)(B)(iv) (1984).

forfeiture provisions).[8] Such a dispute exists here due to Janssen's listing of the '179 patent in the Orange Book.

i. *Mylan Suffers a Judicially Cognizable Injury.*

Without the ability to challenge the '179 patent through a declaratory judgment action, Mylan will suffer "exactly the type of injury-in-fact that is sufficient to establish Article III standing." *See Caraco*, 527 F.3d at 1291-92. As the *Caraco* Court explained, "[s]ince the FDA [could not] approve subsequent Paragraph IV ANDAs until the first Paragraph IV ANDA filer's 180-day exclusivity period expires, the date on which the exclusivity period is triggered is critical to NDA holders and subsequent Paragraph IV ANDA filers." *See id.* at 1284. Indeed,

> if the NDA holder [could] prevent the subsequent Paragraph IV ANDA filer's court challenge, it [could] delay FDA approval of the subsequent Paragraph IV ANDA and thus delay the subsequent Paragraph IV ANDA filer's entry into the market. . . . [A]n NDA holder could thus delay any subsequent Paragraph IV ANDA filer from entering the market until the NDA holder's Orange-Book-listed patents expire.

Id. at 1284-85 (internal citations omitted). Absent the ability to challenge the '179 patent, Mylan will have to wait until after the first filer for the '179 patent launches its product and the first filer's 180 day exclusivity expires before the FDA will be able to approve Mylan's product. *See* 21 U.S.C. § 505(j)(4)(B)(iv) (1984).

Such a launch may never take place. Indeed, assuming that the first filer(s) has reached a settlement agreement with Janssen, there is no guarantee that the first filer(s) will launch after its settlement license date. The first filer may decide not to launch for any number of reasons, such

[8] The Federal Circuit, in *Caraco*, also held that there was a judiciable "case or controversy" so long as the issue was ripe for review and not moot. *See* 527 F.3d at 1291. Janssen did not raise either of these issues in its Motion to Dismiss. As such, Mylan does not address them in detail herein, but reserves the right to seek leave to address these issues in supplemental briefing should Janssen raise such arguments.

as not being able to obtain final approval from the FDA. *See Dey*, 677 F.3d at 1165-66 (rejecting an argument that the case or controversy would cease to exist upon arrival of the date on which the first filer could launch under the settlement agreement because, even if companies settle litigation, the first filer may not launch its ANDA product on the first permissible launch date). If this happens, Mylan's ability to launch its product would be unnecessarily deferred—potentially indefinitely—until after the first filer decides to launch its product. This is "exactly the type of injury-in-fact that is sufficient to establish Article III standing" found to support declaratory judgment jurisdiction in *Caraco*. *See* 527 F.3d at 1291-92.

Janssen's reference to the fact that the '179 patent will expire on the same day as the '798 patent, the patent at issue in the West Virginia litigation, does not negate or render speculative the injury to be suffered by Mylan. (*Cf.* Mot. to Dismiss at 10). The first filer for the '798 patent already launched its product more than six months ago, which means that there is no first filer exclusivity period on this patent blocking Mylan from obtaining FDA approval if the '798 patent is invalidated or if Mylan is found not to infringe its claims.[9] However, there remains a first filer on the '179 patent whose identity is unknown. Accordingly, if Mylan is able to invalidate or obtain a judgment of noninfringement for the '179 patent as well, it will trigger the first filer for the '179 patent to launch its product, clearing the way for Mylan to subsequently launch its product within 180 days of such a launch when the FDA will be free to grant final approval for Mylan's ANDA. *See* 21 U.S.C. § 505(j)(4)(B)(iv).

[9] According to the FDA, Mallinckrodt Inc. ("Mallinckrodt") is the first filer with regard to the '798 patent for its 27, 36 and 54 mg strengths of methylphenidate extended-release tablets. (*See* Kratz Decl., Ex. A at 2-3).

ii. *Mylan's Injury Is Fairly Traceable to Janssen.*

Mylan's injury (threat of delayed entry into the market) is "fairly traceable" to Janssen. The injury all relates back to Janssen's listing of the '179 patent in the Orange Book. *See Caraco*, 527 F.3d at 1291. Indeed, the defendant's

> listing of . . . the patent-in-suit[] in the Orange-Book creates an independent barrier to the drug market that deprives [the subsequent ANDA applicant] of an economic opportunity to compete. It is well established that the creation of such barriers to compete satisfies the causation requirement of Article III standing.

Id. at 1293-94. The "creation of such barriers to compete satisfies the [but for] causation requirement of Article III standing." *See id.*

iii. *Mylan's Injury Can Be Redressed by Permitting It to Maintain Its Complaint.*

Janssen does not appear to dispute that the injury to Mylan can be remedied by maintenance of this action. Indeed, the injury to Mylan is redressable by a declaratory judgment that the '179 patent is invalid or not infringed. *See id.* at 1294 (noting that the ability to obtain such a judgment may "clear the path to FDA approval"). This action can serve to redress the injury caused to Mylan.

IV. CONCLUSION

For the foregoing reasons, Mylan respectfully request that this Court deny Janssen's Motion to Dismiss.

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing document has been served upon the following counsel of record via the Court's CM/ECF notification system, this 30th day of July, 2015:

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